

Title 25. HEALTH SERVICES

Part 1. TEXAS DEPARTMENT OF HEALTH

Chapter 229. Food and Drug

Subchapter F. Production, Processing, and Distribution of Bottled and Vended Drinking Water Use

Amendments §§229.81, 229.82, 229.84, 229.85, 229.87 - 229.91

New §§229.83, 229.86

Repeal §§229.83, 229.86

Final Preamble

The Texas Department of Health (department) adopts amendments to §§229.81, 229.82, 229.84, 229.85, 229.87 - 229.91, the repeal of §§229.83 and 229.86, and new §§229.83 and 229.86 concerning the production, processing, and distribution of bottled and vended drinking water. Sections 229.81, 229.85 - 229.86, and 229.88 are adopted with changes to the proposed text as published in the January 31, 2003, issue of the *Texas Register* (28 Tex Reg 901). Sections 229.82 - 229.84, 229.87, and 229.89 - 229.91 are adopted without changes, and therefore will not be republished.

An amendment to §229.81 adds definitions for clarification of the regulation. Duplicative language was deleted in §229.82. New §229.83 inserts the reference to the Texas Commission on Environmental Quality regulations on water hauling. An amendment to §229.84 updates the section title name. An amendment to §229.85 updates examples for labeling and advertising. New §229.86 reorganizes the section for clarity and adds a requirement for submission of sample results to the department. An amendment to §229.87 updates the reference to the Texas Commission on Environmental Quality. An amendment to §229.88 clarifies oversight of bottling and vending operations by a certified individual. An amendment to §229.89 adds a timeline for completing the bottled and vended water certificate examination within a limited time frame. An amendment to §229.90 updates the section title for clarification. Amendments to §229.91 update references to the department's hearing procedures and correct spellings to be consistent within the regulation.

Government Code, §2001.39, requires each state agency to review and consider for readoption each rule adopted by that agency. The current rules have been reviewed and the department has determined that reasons for adopting the sections continue to exist; however the rules need revisions as described in the preamble. Sections 229.83 and 229.86 are repealed, and new sections are adopted.

The department published a Notice of Intention to Review §§229.81 - 229.91 in the *Texas Register* on March 22, 2002 (27 Tex Reg 2265). No comments were received as a result of the publication of this notice. Over 300 stakeholders were subsequently notified by mail that these rules were under review. Comments were submitted as a result of this mailing and were taken into consideration when drafting the proposed rules.

The following comments were received by the department during the official comment period concerning the proposed sections. Following each comment is the department's response and any resulting change.

**Comment:** Concerning §229.81(c)(14)(B), several commenters stated that deleting the word “unit” in the definition of “vended water” changes the meaning to include all sorts of waters.

**Response:** The department disagrees with these comments. The department feels the terms “unit” and “servings” are redundant, therefore “unit” was deleted in the proposed rules. No change was made as a result of these comments.

**Comment:** Concerning Section §229.81(c)(16), several commenters stated that definition of “water dispensing device” expands bureaucracy and is too vague. One commenter added, “What is your purpose?”

**Response:** The department disagrees with these comments. This definition was only added to provide some clarity on requirements for vending machines and bottled water stores. Under the current rules, requirements for both vending machines and bottled water stores were combined in §229.86. This section can be confusing because some of the requirements only apply to vending machines, not the store facilities. Since not all the requirements applied to vended water stores, the term “water dispensing device” was created, and §229.86 was divided into §229.86(a) and §229.86(b) to provide better differentiation on requirements between the two types of facilities. No additional regulatory requirements were added on bottled water stores or vending machines due to the addition of this definition. No change was made as a result of these comments.

**Comment:** Concerning §229.83, several commenters recommended the removal of the wording that places jurisdiction of water hauled for bottled water from the Texas Commission on Environmental Quality's (TCEQ) jurisdiction as the department has sole jurisdiction over the production of food products including bottled water. The commenters also asserted that bulk hauled water is not drinking water and that deletion of this rule will not adversely impact health or safety.

**Response:** The department disagrees with these comments. The TCEQ regulates drinking water from its source to the point of the plant or dispensing device. As all water used in bottled and vended water must be from an approved source, the water at the point of source must be treated and therefore already meets the TCEQ's requirements for drinking water. While it is true that the department regulates food and beverages and their ingredients from the point of production through to the consumer, there is already a TCEQ regulation in place for hauling drinking water. The department feels there is no reason to create an additional or conflicting regulation. This department rule complements and does not conflict with the TCEQ rules. The deletion of this wording would remove any regulation of the tankers transporting water destined for bottled and vended water facilities. The department feels this could cause confusion and would have an impact on health and safety. The department does agree that there is confusion on the definition of “drinking water.” A definition of “drinking water” has been added in §229.81(c)(6).

**Comment:** Concerning §229.83, several commenters stated that microbiological standards stated in §229.84 allow for flexibility on disinfection methods for transport. These commenters also stated that §229.83 is in direct conflict with federal regulations governing disinfection byproducts in bottled water and deletion would remove the requirement to test for disinfection byproducts in the source water.

**Response:** The department disagrees with these comments. Section 229.84 states, “Bottled and vended water production including transporting... shall be conducted under such conditions and controls as are necessary to minimize the potential for microbiological contamination... These conditions and controls shall include the following. (1) bottled and vended water shall be subject to effective germicidal treatment...”. The commenters are requesting the removal of the treatment for the hauling of the water prior to plant production. Section 229.84 does allow for flexibility; however, this flexibility does not allow for no treatment and, as stated in the comment, would conflict with rules already in place for the transportation of drinking water. TCEQ regulation 30 TAC §290.42(b)(1) already requires disinfection of water at the source in order to obtain source approval. The reference to TCEQ water hauling regulations ensures disinfection residual through transportation. As the disinfection begins at the source, the requirement for testing disinfection byproducts of source water would not be eliminated by removing this section. There are methods during the processing of bottled and vended water to reduce the chlorine to an acceptable level in the finished product. Therefore, this rule is not in direct conflict with federal regulations. No changes were made as a result of these comments.

**Comment:** Concerning §229.84(2) and (3), several commenters recommended a change to this section allowing water to be filled in lines used for other beverages. The comments include the addition of a requirement for a Clean in Place (CIP) system or the equivalent to sanitize the lines prior to use for bottled water. The commenters assert with this change that firms prepare and follow a Hazard Analysis Critical Control Point Plan (HACCP).

**Response:** The department disagrees with these comments. The current rules do not require HACCP for bottled water facilities. To require such a system to be put in place at this time would require extensive start-up and training expenses for bottled water facilities. Since the requirement for dedicated lines has been the regulation in Texas for the past 15 years, industry in Texas is in general compliance at this time. No changes were made as a result of these comments.

**Comment:** Concerning §229.85(b), a commenter stated, “It should be specified that this subsection (b) applies to bottled water only since vending machine owners do not necessarily have control over the bottles being provided for use at the machine.”

**Response:** The department disagrees with this comment. Labeling is only required for food in packaged form. Since vending machines do not sell water already in packaged form, there is no requirement for labeling, therefore this section does not apply. No change was made as a result of this comment.

**Comment:** Concerning §229.85(b), several commenters request the deletion of the source labeling requirement. These commenters assert this is in violation of the Federal Food, Drug and Cosmetic Act (FFDCA) 403A, and the Commerce Clause of the U.S Constitution and, as such, is preempted.

**Response:** The department disagrees with these comments. Federal preemption requirements described in FFDCA 403A do not apply to geographic source labeling. Section 403(A)(1) of the FFDCA preempts the states and locals on the name of the food if it has a “standard of identity.” FFDCA 403(A)(1) only preempts the names of these waters and what they stand for. That is what a “standard of identity” means. As long as the "standards of identity" for the various types of waters are in conformance (i.e. "Deionized Water," "Distilled Water," "Purified Water," etc.), states are permitted to have other types of labeling requirements for these waters, including source labeling. Requiring manufacturers to label the source of the product has nothing to do with a "standard of identity." The Commerce Clause of the U.S. Constitution does not apply in the matter of source labeling. Source labeling is required only for manufacturers of bottled water in the State of Texas. Manufacturers of bottled water in other states do not have to comply with these requirements. No change was made as a result of these comments.

**Comment:** Concerning §229.86(b)(3), two commenters did not agree that vending machines should be equipped with self-closing, tight-fitting doors. A commenter understood why this could be required for outdoor machines, but not for the machines kept indoors. The commenter suggested that a sneeze guard should be adequate indoors. Another commenter stated that machines with dispensing nozzles that are inaccessible when the machine is not dispensing water should be allowed.

**Response:** The department partially agrees with these comments. First, the purpose of this section of the regulation is to protect the dispenser from environmental contamination. Even if a vending machine is placed indoors, it may be in an area with high traffic or where it is exposed to handling or cross drafts. Therefore, the department believes the reason for the protective door requirement remains. The department does not believe a sneeze guard meets this requirement. Second, the department considers vending machines that have a design such that the dispensing nozzle is protected by a mechanism that isolates the dispenser by an internal door when not in use, to be in compliance with this portion of the regulation. No change was made as result of these comments.

**Comment:** Concerning §229.86(c)(2), a commenter recommended that if the water used in the vending machine is from an approved source per state and local government agencies, why should the language, “...and if required by the department, shall also be analyzed for other physical, chemical, or microbiological parameters...” be added.

**Response:** The department disagrees with this comment. The department recognizes that approved sources are required to maintain certain physical, chemical, or microbiological test results. The department includes this language in the regulation to allow the department to do testing in cases where water from a particular facility is believed to be have contaminated. In the case of vended

water, this language does not require any additional routine testing other than the monthly bacteriology testing. No change was made as a result of this comment.

**Comment:** Concerning §229.86(c)(2)(A), a commenter recommended that the “testing lab or agency should be responsible for reporting POSITIVE TEST results to Austin rather than the vendor.”

**Response:** The department disagrees with this comment. The vendor is responsible for testing the water and ensuring it is safe to distribute to the public. The department feels it is the vendor’s responsibility to notify the department if water from their facility tests positive. In addition, the department does not have statutory authority to require private laboratories to submit sample results. No change was made as result of this comment.

**Comment:** Concerning §229.86(c)(2)(A), a commenter suggested that positive tests results be e-mailed in place of faxing.

**Response:** The department agrees with this comment. An option for e-mailing the positive test results has been added to this section.

**Comment:** Concerning §229.86(c)(2)(B), several commenters requested deletion of this section.

**Response:** The department disagrees with these comments. The department was approached during the rulemaking process to reduce the sampling interval on water dispensing devices. The department does not have enough data to determine the public health impact of this request. This section was added with the intent of requiring vendors to submit all sample results for the period of one year from the date of the rule implementation to obtain the needed data. After one year, the requirement to submit negative sample results to the department will be removed. No change was made as a result of these comments.

**Comment:** Concerning §229.86(c)(2)(B), a commenter suggests that a single, complete file of results be e-mailed within five business days of the end of each month.

**Response:** The department agrees with this comment. The section has been changed to allow negative sample results for one month to be sent in bulk within ten calendar days of the last day of the month. In addition, an option was added for e-mailing the test results.

**Comment:** Concerning §229.86(c)(5)(A), a commenter suggested that if the water sample is positive for coliforms, the machine should be disinfected and then a second sample taken. Also, the commenter recommended changing the verbiage “...one sample per day during a four consecutive-day period...” to three days later after disinfecting based on the assumption that the vending machine is using a reverse osmosis membrane in the purifying process. If the water is not processed by reverse osmosis, then the original rule would apply. The commenter stated, “Where can E-coli come from in these machines?” Another commenter recommended a single retest within 24 hours of

notification of a positive coliform, without shutting the machine down. Should the retest be positive, the machine must be shut down, the “entire” machine sanitized, then a sample of the vended water and the source water be submitted. Both samples must be coliform negative in order to allow the machine to return to operation. Another commenter stated, “The four consecutive-day requirement is difficult to achieve without significant and unnecessary down time. For example, if we are notified of a positive sample on a Wednesday, in order to meet the four consecutive-day requirement, we would have to wait to begin repeat sampling until the following Monday.” The commenter suggested that the repeat sampling should be completed on the same day.

**Response:** The department agrees with these comments. Regarding §229.86(c)(5)(A) - (C), subparagraphs (A) and (B) were amended, and subparagraph (C) was added to reflect the wording recommended by the Association of Food and Drug Officials model regulation for vended water.

**Comment:** Concerning §229.86(c)(5)(B), one commenter suggested eliminating this section or changing it to state, “GO GET ANOTHER SAMPLE as long as it is in the time frame required, i.e. monthly.” Another commenter recommended deleting this section. The commenter stated, “A repeat test from water vending machines that have initially tested positive for coliform bacteria is an appropriate monitor of sample collection techniques.”

**Response:** The department agrees with these comments. Regarding §229.86(c)(5)(A) - (C), subparagraphs (A) and (B) were amended, and subparagraph (C) was added to reflect the wording recommended by the Association of Food and Drug Officials model regulation for vended water.

**Comment:** Concerning §229.86(c)(2), several comments were received regarding bacteriological sampling of each water dispensing device. The commenters stated that this is very costly, and if the source of the water is the same for each dispensing device, why have to test each device?

**Response:** The department agrees with these comments in that the wording in the definition for a water dispensing device is not clear. The definition has been changed in §229.81(c)(17) to specify a water dispensing device as each unit that filters and disinfects the water for dispensing. The department did not intend for the definition to include each faucet in the case of a vended water store. However, each vending machine is a separate water dispensing device.

**Comment:** Concerning §229.88(a) and (b), a commenter recommended clarifying this section. The commenter stated that “§229.88(a) seems to require a vended water operator to hold a certificate...; however, (b) appears to allow an operator to run a system as long as he/she is being guided by someone who holds a certificate...”

**Response:** The department disagrees with this comment. The rule actually states the opposite. Section 229.88(a) requires that a bottled water facility have full-time supervision by a certified bottled water operator. The record keeping and sampling requirement for bottled water are more involved than vending. Section 229.88(b) requires that vending operations have a certified bottled and vended water operator guide the operation and be available whenever there are problems. No

change was made as a result of this comment.

**Comment:** Concerning §§229.88 - 229.89, several commenters requested the expansion of this section to include acceptance of the International Bottled Water Association's (IBWA) Certified Plant Operator Program. The commenters also requested that the department standardize its program to follow the IBWA's certifying program.

**Response:** The department disagrees with these comments. The Texas Health and Safety Code, Chapter 441, Regulation of Bottled and Vended Drinking Water requires the department to provide for the testing of the applicant and issue a certificate of competency. It does not give the department the authority to allow for third party testing or reciprocity of third party certifications. No change was made as a result of these comments.

**Comment:** Concerning §§229.88 - 229.89, a commenter requested a change in the section to include two separate tests, one for water vending operators and a second for bottled water operators.

**Response:** The department disagrees with the comment at this time. However, we are studying the issue for future consideration. No change was made as a result of this comment.

**Comment:** Concerning the legend for the proposed rules, one commenter stated, "A new legend hidden in the text before paragraph §229.83 is a violation of order, common sense, standard procedure, and usual purpose. Why publish proposed changes if they are going to be camouflaged?"

**Response:** The department disagrees with this comment. A department copy of the proposed rules was forwarded to the commenter which included a legend to determine the underlining of new rule text, brackets for rule text being deleted, and (No change.) for rule text not being changed. The legend is department format which is almost identical to the *Texas Register's* weekly publication of rules that explains and utilizes the underlining, brackets, and (No change.) language at the beginning of proposed rules. No change was made as a result of this comment.

The commenters were: Culligan Store Solutions, Danone Waters of North America, Glacier Water, International Bottled Water Association, National Automatic Merchandising Association. In addition, numerous individuals commented. All commenters were not against the rules in their entirety, however, expressed concerns, asked questions, and suggested recommendations for change as discussed in the summary of comments.

The department is making the following changes due to staff comments.

**Change:** Concerning §229.88, a period was added at the end of the first sentence of the rule text.

**Change:** Concerning §229.85(b), a statement was added to clarify that water processed by deionization, distillation, or reverse osmosis that renders the water "purified" as defined by §229.81(c)(11) are not required to declare the source of the water.

The amendments, repeal, and new rules are adopted under the Health and Safety Code, §431.241, which provides the department with the authority to adopt necessary regulations pursuant to the enforcement of Chapter 431; and §12.001, which provides the Texas Board of Health (board) with the authority to adopt rules for the performance of every duty imposed by law on the board, department, and the commissioner of health.

#### Sections for Repeal

§229.83. Water Hauling.

§229.86. Processing of Vended Water.